The urinary tract is the most common site of nosocomial infection, accounting for more than 40% of the total number reported by acute-care hospitals and affecting an estimated 600,000 patients per year. Most of these infections—66% to 86%—follow instrumentation of the urinary tract, mainly urinary catheterization. Although not all catheter-associated urinary tract infections can be prevented, it is believed that a large number could be avoided by the proper management of the indwelling catheter. Additionally, clinicians are now examining the design of the urinary drainage system, including its ability to safely and promptly drain urine from the bladder into a reservoir, its ability to prevent backflow of urine from the drainage system into the bladder, and its influence on the risk of catheter-associated UTI. Safe Practices convened a panel of expert clinicians to respond to questions about urinary drainage systems and the potential for catheter-associated UTI risk. In order to gain a better understanding of these issues, a panel of expert clinicians—a urologist, urological nurse practitioners, a clinical nurse specialist, and a wound, ostomy and continence nurse—was asked to respond to 7 questions about urinary drainage systems. Specific questions focused on design features of optimal urinary drainage systems, challenges faced by patients managed by short- and long-term indwelling catheters, and the potential for urinary drainage systems to reduce UTI risk.

Symposium: Consensus and controversy in urinary drainage systems: Implications for improving patient safety

**Moderator** Mikel Gray PhD, FNP, PMHNP, CURN, CCRN, FAAN

**Panelists**
- Angela C. Joseph RN, MSN, CRNP, FAANP, FAAN
- David M. Mercer RN, MSN, APRN-BC, CFCCN, CWOCN
- Diane K. Newman RNC, MSN, CRNP, FAAN
- Eric Rovner MD

Diane Rovner: The ideal characteristics of an overnight urinary drainage system for patients with an indwelling urinary catheter?

Rovner: The ideal characteristics of an overnight urinary drainage system should be easily, comfortably, and securely attached to the patient without causing strap-related skin problems such as pressure necrosis. The straps should maintain catheter tubing securely and avoid excess tension and pressure on the soft tissue of the genitourinary tract. The components of the tubing and drainage system should be hypoallergenic and non-reactive. The materials used for construction should be strong, durable, and washable and should not retain odor. The collection bag should be large enough to contain the entire volume of nighttime urine output without the need to be emptied overnight. The mechanism for emptying the bag should maintain...
a closed system while being emptied, be easily opened and closed, and be secure from leakage while closed.

Optimally, the system should reduce the potential for infection. There should be a mechanism for changing from a nighttime to a daytime drainage bag (leg bag) that maintains a closed system as much as possible. In addition, the collection device should contain a mechanism for the one-way flow of urine away from the patient. Ideally this would be a valve system for the prevention of backflow of urine from the bag into the tubing and subsequently the patient. If the catheter and tubing are expected to remain indwelling for an extended or indefinite period, there should be an easily accessible port by which a urine specimen can be obtained for culture and analysis, if clinically indicated, without breaking the closed system. Importantly, the tubing should be of sufficient strength to avoid kinking with resulting retention of urine. Ideally, the system should be constructed from materials with intrinsic anti-bacterial and anti-encrustation properties (e.g., preventing biofilm production).

Joseph: Individuals should have a comfortable system that allows them movement without dislodgement of the catheter and irritation or injury to the bladder neck. The system needs to enable constant drainage of urine away from the bladder without pooling, since the individual will be sleeping and not aware of impedance of urinary flow. Urinary tubing should be sufficient in length to allow the collection device to be secured on a non-moving part of the bed frame. Individuals need to have ease in emptying as well as securing urine in the bag. Catheters need to be placed in individuals who have exhausted less invasive interventions or who are unable to perform other treatment interventions. Use of indwelling catheters should be minimized.1,2

Mercer: I agree that a design that safely and effectively evacuates urine from the bladder in order to provide minimal disruption to sleep is essential. The ideal system should also take into account various sleeping habits, such as tossing and turning versus static sleeping, and have features designed to minimize twisting, kinking, or disruptions in urinary flow. The overnight drainage bag must contain a closed system as much as possible. In addition, the collection device should contain a mechanism for the one-way flow of urine away from the patient. Ideally this would be a valve system for the prevention of backflow of urine from the bag into the tubing and subsequently the patient. If the catheter and tubing are expected to remain indwelling for an extended or indefinite period, there should be an easily accessible port by which a urine specimen can be obtained for culture and analysis, if clinically indicated, without breaking the closed system. Importantly, the tubing should be of sufficient strength to avoid kinking with resulting retention of urine. Ideally, the system should be constructed from materials with intrinsic anti-bacterial and anti-encrustation properties (e.g., preventing biofilm production).

Newman: Leg bags are commonly used during the day in patients who are ambulatory. More active patients may prefer a leg bag for use at home or when away from home because these bags allow more freedom of movement. They come in different sizes (horizontal or vertical) and are made from a variety of materials (vinyl, latex, and others). Reusable leg bags are also available. These smaller bags are more discreet because the person can attach the bag to the upper thigh or calf and conceal it under clothing. But placement of the bag on the body is important, as a bag of urine can be difficult to accommodate discreetly and can present problems with appearance (bulge) and noise (slosh).4 The calf is usually the easiest place to attach a leg bag, and women who wear skirts may use a thigh bag or waist belt. Some leg bags have a fabric backing against the skin to reduce sweating.

Rovner: Factors related to ideal daytime indwelling catheter systems include most of the characteristics as those advocated for overnight catheters with 1 important addition: the tubing length should be easily adjustable to promote patient comfort especially as regards clothing (e.g., short pants versus long pants).

Gray: Although urinary drainage systems rely on gravity to evacuate urine from the bladder vesicle to the drainage bag, limited evidence suggests that the magnitude of negative pressures generated at the eye of the catheter may be quite high. These pressures may pull the mucosa into the eye of the catheter, resulting in localized damage, sometimes referred to as suction lesions. In controlled experiments using an animal (pig) model, 18-French latex or all-silicone indwelling catheters were clamped and the bladder was filled with 80 mL of sterile saline warmed to approximate body temperature.5,6 The catheter was attached to a urinary drainage system and the bag was placed 40 cm (about 16 inches) below the level of the bladder outlet. The clamp was removed and the bladder drained using gravity alone. Histologic studies demonstrated localized areas of inflammation characterized by edema and elevation of the mucosa and submucosa, and some thinning of the urothelium. The researchers noted that these areas appeared grossly similar to polypoid cystitis, a condition commonly observed in patients managed by long-term indwelling catheterization. McDonald et al7 compared cystoscopic results in a group of 105 patients managed by an indwelling catheter. Fifty were

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- Rovner -

bag should contain 1500 mL or 2000 mL, with a long tube to facilitate overnight bladder drainage. The bag should be positioned below the bladder, allowing urine to drain easily.3

What are the characteristics of the ideal daytime drainage system for ambulatory patients managed with an indwelling urinary catheter?

Mercer: Daytime urinary drainage systems must assume that users will be as active, busy, and productive as persons without indwelling catheters. Designing at this level will reach the entire continuum of patients meeting the criteria for drainage devices, from a marathon runner to a quadriplegic in a wheelchair. I agree with Angela that the ideal system also must be portable, lightweight, easy to empty, odorless, discreet, and effective, and must take into account variable body positions.

What is the impact of dynamic flow problems on patient and care providers?

Joseph: I would emphasize that issues of movement, concerns about dislodgement of the catheter, irritation or injury to the bladder neck, and cosmesis need to be incorporated into the ideal daytime drainage system. Efficient urinary drainage while preventing backflow is even more of an issue during waking hours. For example, sitting may partially compress tubing, rendering it even more important to maintain the drainage system below the bladder.

The valve to empty the urine from the bag should be readily accessible and easily opened and closed, especially for those with limited hand function. A cap should be secured onto the end to prevent dripping of urine if the valve becomes partially open, and components of the system should be non-latex to avoid hypersensitivity responses.
managed by non-vented drainage systems, and 52 were managed by a urinary drainage system that incorporated a top-vented line system, which incorporates a vented airflow system at the connection between catheter and connecting tubing that allows air to enter the drainage system, preventing elevated negative pressures. A filter prevents airborne bacteria from gaining access to the urinary drainage system and prevents urine leakage. Cystoscopy performed between 20 minutes and 7 days following catheterization revealed localized areas of inflammation, described as suction lesions, in patients managed with non-vented systems but no lesions in those managed with vented systems.

Mercer: Dynamic flow problems may place patients at risk for incomplete bladder evacuation and various inflammatory conditions. The presence of large residual volumes in the bladder may increase the risk for catheter-associated UTIs with the potential for sepsis. In addition, high intravesical pressures may lead to urinary reflux to the kidneys, resulting in damage to the upper urinary tract.

Newman: Dynamic flow problems may occur whenever the drainage bag does not promote adequate urine drainage. It is considered standard clinical practice to maintain the drainage bag below the level of the patient’s bladder, but the drainage tubing should be maintained above the level of the collection bag. We also recommended that urinary drainage bags are hung on an appropriate stand to prevent direct contact with the floor.

Joseph: I would add that urinary drainage is position-dependent, especially for those in wheelchairs. I have observed that urine may not easily flow into the drainage device during necessary positional changes. This is especially evident in the tilted wheelchair, since urine must flow uphill to the collection device when individuals are in the tilted position.

Is there any evidence that aspects of urinary drainage system design, such as antireflux valves, drainage ports, tapered connections, or drainage tube features, reduce the risk of urinary tract infection?

Rovner: There is only scant evidence that any particular design modifications reduce the risk of UTI in chronically catheterized patients. There is no level-1 evidence that properly securing a catheter and drainage system reduces UTI risk in the short or long term. Nevertheless, this is probably good clinical practice in that it reduces trauma to the lower urinary tract and urethra, reduces bladder and urethral mucosal trauma, and maintaining good hygiene while manipulating the catheter are all important adjuvant measures.

Though silver alloy catheters seem to reduce the risk of UTI in the short-term catheterized patient, this has not been proven to be of benefit in the long-term catheterized patient. Furthermore, whether the addition of silver alloy would be of benefit in the construction of tubing and urinary drainage collection devices is, as of this point, unknown.

Joseph: Efforts to protect the integrity of the internal system may lower the risk of bacterial contamination. A laboratory-based study by Wenzler-Röttele and colleagues found a decrease in bacteria traveling from collection device to bladder when using a double non-return valve as opposed to a single one. Many individuals that I have treated believe that the anti-reflux valve impedes the flow of urine. They report urine leakage caused by catheter bypassing (leakage from the urethra around an indwelling catheter) or pressure-induced leakage at the catheter-drainage tubing connection. As a result, some removed the double non-return valves.

From 14 years of clinical practice in a nurse-run catheter-change clinic, I have formed an opinion that catheter-associated UTIs are associated with obstructed urine drainage. Common causes include drainage tubing becoming caught on the corner of the bed, table, or wheelchair, which slightly dislodge the urinary catheter and impede the urinary flow; overweight or obese individuals compressing tubing with the weight of their bodies while sitting; or patients concealing the drainage system on their laps, slowing the flow of urine from the bladder.

Mercer: Although there is a paucity of robust clinical evidence, clinical experience supports an association between design of drainage systems and UTI risk. For example, there is widespread acceptance among experts that we should maintain the integrity of drainage systems (closed system) to prevent bacterial ascension intraluminally to the bladder. A great deal of work in this area has been performed by Kunin, suggesting that engineering catheter systems to reduce infection risk is quite possibly overemphasized. Rather, clinicians should focus on asking the question “Is this catheter needed?” and we should direct our efforts at alternative voiding solutions: condom catheters, ultrasound to determine bladder volumes, etcetera. This is a very timely and current debate. Further research in this area is particularly relevant given the Centers for Medicare and Medicaid

Cystoscopy performed between 20 minutes and 7 days following catheterization revealed localized areas of inflammation, in patients managed with non-vented systems but no lesions in those managed with vented systems.
Newman: I agree with the opinions expressed by my colleagues and think it worthwhile to summarize a few portions of the limited evidence concerning several areas of drainage-system design, including anti-reflux valves, pre-connected drainage systems, and bag design.

Pre-connected drainage systems
Classen et al. evaluated an approach combining meatal care, disinfection of the drainage portal, and a pre-connected drainage system is no more effective than the use of a pre-connected catheter alone.

Wille et al. compared the time of onset and incidence of nosocomial bacteriuria between 2 different closed urinary drainage systems: a simple closed-drainage system containing an anti-reflux valve, and a complex closed-drainage system incorporating a pre-connected coated catheter, a tamper-discouraging seal at the catheter-drainage tubing junction, a drip chamber, an anti-reflux valve, a hydrophobic drainage bag vent, and a povidone-iodine-releasing cartridge in line with the outlet tube of the urine collection bag. Results revealed no differences between the 2 urine drainage systems in the incidence or time to onset of nosocomial bacteriuria.

Gray: I agree that evidence linking design features of urinary drainage systems to a reduced risk of UTI is limited. Nevertheless, the panel’s comments are encouraging because they emphasize several aspects of systems designed to lower the risk of UTI. I was intrigued to read a study set in a healthcare system that experienced a planned transition from widespread use of open urinary drainage systems to the closed systems commonly used in North America. Allepuz-Palau et al. performed a secondary analysis of data from the EPINE database (which studied the prevalence of nosocomial infections in Spain). They used a logistic regression model to associate incorporation of a closed urinary drainage system and catheter-associated UTI prevalence. Hospitals that fully incorporated a closed urinary drainage system experienced a statistically significant and clinically relevant decrease in the prevalence of UTI. While this type of analysis is no longer feasible in the United States, the experience of colleagues from Spain provides a timely reminder of the potential for urinary-system drainage design to reduce UTI risk.

What are the indications for selecting a urinary drainage system that incorporates a urine meter?

Mercer: Indications for selecting urinary drainage systems include all situations where medical management and decisions rely on current, minute-by-minute quantification of urine output. This includes but is not limited to acute myocardial infarction, hemodynamic instability, massive fluid resuscitation, major surgery, major trauma, acute renal disease, pulmonary critical care, acute brain injury, neuroendocrine disorders, and diuretic therapies with associated urinary incontinence.

Urine meters have similar function regardless of manufacturer; each varies, however, in respect to how the measuring devices are emptied into the urine collection bag. The urine meters must maintain a closed system and must be easily readable. There is evidence suggesting that how the urine flows into a collection bag from a meter may influence bacterial growth patterns. Most systems must be tilted to empty urine back into a collection bag. Other systems have anti-return valves at the bottom of urine meters. Such differences may influence why a clinician chooses one over another.

Rovner: We also find use of a urine meter is helpful, if not essential, when it is necessary to monitor urine output on an hourly basis in a variety of clinical scenarios. This is most often applicable for the critically ill patient in the intensive care unit (ICU), or in the operating room and post-anesthesia care unit following surgery. However, in other settings where urine output monitoring is critical—such as in cases of sepsis, congestive heart failure, extensive burns, and hemodynamic instability—the urine meter is important in assessing the success of the ongoing resuscita-
tion effort.

Joseph: Following major surgery, it is imperative to know hourly output to monitor the function of the kidneys. Also, if there is a question of renal failure and the ability of the individual to make urine, then a urine meter is important to assess hourly output. Many individuals who are in ICUs have the need for hourly output measurements to assess their basic bodily functions. The urine meter should have the following: (1) bold markings that are easy to read, (2) ease of attachment to the larger urine collection device, and (3) the alternative of emptying urine into the larger collection bag or emptying it directly from the urine meter. Since exact measurement of the urine is critical and will determine future treatment, the urine meter needs to contain urine without the threat of leakage due to cracking or faulty valves. The ability of healthcare staff to accurately read the meter and collect small amounts of urine would affect the clinician’s choice of meter: reliability is key.

Newman: The Lubricath® (C.R. Bard) and Dover® (Covidien,) Urine Meter Foley Tray products, includes a lubricated catheter, urine meter, and catheter insertion tray (Figure 1). Their urine-meter indwelling-catheter trays are also available with an outlet device, which eliminates urine splash when emptying the drainage bag.

What is the optimal regimen for cleansing and reducing bioburden in reusable urinary drainage systems in patients with long-term indwelling catheters?

Joseph: Dille et al18 did classic research on cleansing of urinary bags and recommended the following regimen: (1) drain urine from the bag; (2) vigorously agitate clean water in the collection bag twice; drain after each instillation; (3) pour a diluted solution of chlorine bleach (1:10) on drainage spigot, spigot bell, sleeve, cap, and connector; (4) also pour the bleach solution into the bag and vigorously agitate it for 30 seconds, then allow it to drain and air dry. This resulted in decreased colony counts. This regimen has been recommended in peer-reviewed bladder-care guidelines and has been established as best practice.19,21

Rovner: Any process that reduces encrustation and biofilm formation is potentially beneficial in patients with long-term indwelling catheters. Unfortunately, we have very little evidence to support any particular cleansing regimen, including the commonly utilized dilute-vinegar solutions, bleach, or antibiotic irrigations. Such measures do not seem to reduce the risk of UTI but do seem to subjectively reduce odor emanating from the drainage systems. There is anecdotal evidence that short-term irrigation with some types of solutions may reduce encrustation; however, there is no level-1 evidence to support such activities. It is likely that the increased fluid throughput, regular cleansing, and catheter changes that are associated with these behaviors make drawing definitive conclusions from these practices exceedingly difficult due to these confounding factors.

Mercer: Recommended solutions for cleaning urine drainage bags include variations in strength of vinegar or bleach. One part vinegar to 3 parts water (1:3) is a common cleaning solution. For bleach, 4 ounces of bleach to 1 gallon of water is an acceptable solution. Solutions should be instilled down the tubing and into the bag using an appropriate device such as a spigotted water bottle. Agitate the solution for 30 seconds to a minute. This should be repeated at least every other day. Empty the bag and allow thorough drying.

Newman: Several studies have shown the benefit (i.e., decreasing bacteriuria) of a bleach mixture used to irrigate drainage bags in patients with long-term indwelling catheters.19,22 However, bleach is a toxic agent and many clinicians discourage its use. The use of a diluted hypochlorite solution (1 part hypochlorite to 10 parts water) has been recommended.21 Others recommend a vinegar solution of 1 part vinegar to 3 parts water. Bleach has been shown to be more effective than vinegar or other solutions in urine-bag decontamination; the benefit of vinegar is primarily aesthetic because it curtails odor.4 A systematic review suggested that adding antibiotic or antimicrobial solutions (e.g., hydrogen peroxide, silver sulfadiazine) to the bag has no effect on catheter-associated UTI and is therefore not recommended.23

The design of the drainage port may contribute to cross-infection, particularly with regard to ease of emptying and contamination of the hands of the person emptying the bag. Some clinicians recommend emptying the bag frequently, when it is no more than half full, to prevent backflow into the bladder and thus minimize bacteriuria. The 2003 NICE24 guidelines recommended that drainage bags should be emptied frequently enough to maintain urine flow and prevent reflux.

Prior to changing or emptying a drainage...
bag, the person who is performing this task should wash hands and use clean non-sterile gloves. As for the receptacle into which the drainage bag is emptied, there appears to be clinical acceptance of various types but no evidence-based research. The bag can be emptied in a toilet or commode (this may be appropriate in a home-bound patient) or into a clean receptacle. Most guidelines recommend a separate and clean container for each patient (especially in a hospital setting) and avoidance of contact between the drainage port and container. Some recommend cleaning the drainage port with an isopropyl alcohol swab before opening and after closing but, again, the correct procedure for bag emptying remains controversial. A standard clinical practice is to change the drainage bags every 5–7 days, but there is little research to support this. Some clinicians feel that the bag can be used up to 1 month if it is cleaned with a water and bleach mixture.

What is the optimal system for securing a Foley and urinary drainage system to the leg?

Rovner: There are a number of characteristics for the optimal urinary drainage-bag security or strap system. These include a non-slip, adjustable, and comfortable system that is easily secured to the patient’s leg at the level of the thigh. The goal is to minimize catheter mobility as it exits the urethral meatus, but, at the same time, to avoid excessive tension. The strap material should be easy to clean, durable, hypoallergenic, and non-reactive. The leg bag should likewise be secured to the patient so as to minimize the potential for trauma.

Joseph: Securing the catheter and leg bag to the body necessitates a method that permits unobstructed flow of urine... (quote)

- Joseph -

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Mercer: Many securement devices are available, including adhesive or non-adhesive fixation devices or catheter-specific anchors. Adhesive devices typically anchor the catheter at the Y-bifurcation, thus securing the catheter to the patient. Elastic straps, often cost-effective for health systems, have limited efficacy due to mobility of the devices—the straps slide up and down the leg. The optimal system should be comfortable for the patient, non-irritating to skin while in position, non-traumatizing to skin at removal, effective at maintaining catheter position, and providing a means of easily lodging or dislodging the catheter.

Newman: The optimal system is one that secures the leg bag to a person’s leg securely so it cannot drop suddenly, pulling on the catheter and traumatizing the urethra and bladder neck. Therefore, a leg bag should be attached to the upper thigh or calf, held in place with straps, mesh, elastic straps with Velcro-type closures, or knitted bag holders. Patients who do not want to use straps can secure the bag in place using a net sleeve or stocking, or cloth briefs or leg holders. The calf is usually the easiest place on which to strap a leg bag so it can be concealed under clothing, but women who wear skirts will need to use a thigh bag or a waist belt. Straps that are too tight can restrict circulation, resulting in lesions.

Use of catheter valves

In some countries, such as the United Kingdom, urinary catheters in certain patients are attached not to drainage bags but to catheter valves. A catheter valve (CV) is a small device similar to a drainage-bag port that fits in the end of an indwelling catheter. It has an open-and-close mechanism and is used in place of a drainage bag. Urine is stored in the bladder rather than in a bag and is drained intermittently by releasing the valve. CVs have been used with urethral and suprapubic catheters. The catheter can be attached to a drainage bag at night to drain the urine while the person is asleep. It is thought that the use of a CV may maintain bladder capacity, function, and tone; may decrease urethral erosion because there is no added weight from a drainage bag; and may decrease migration of bacteria from drainage bags.

CVs allow the bladder to fill and empty, mimicking its natural activity. Patients who have intact bladder sensation can feel when the bladder needs emptying and can open the CV to release urine. It is recommended that individuals with neurologic bladder dysfunction open the CV every 3 hours; this routine may also be helpful in reestablishing voiding before removing a catheter. CVs may allow a person more independence because a drainage bag is not attached; however, there may also be an increased risk of infection with CVs because of urine stasis.

There is very little recent research on the use of CVs, especially long-term use. German et al found no difference in the reported incidence of bladder spasms or discomfort and no difference in positive urine cultures when comparing the use of CVs and drainage bags in men with spinal-cord injury (SCI); however, in this study there was a slightly higher incidence of nocturnal frequency and bypassing episodes. Subjects preferred to use the CV, reporting that it felt more comfortable and discreet. Many patients do not like the sensation of urine sloshing about when using a leg bag; the authors suggested that a combination of a valve during the day and an overnight bag may be the ideal solution.

References

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